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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/248,964	02/12/99	WUCHERPFENNIG	K HAR-005

021323 HM12/0312  
TESTA, HURWITZ & THIBEAULT, LLP  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON MA 02110

EXAMINER	
DECLOUX, A	
1644	15

DATE MAILED: 03/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/248,964</b>	Applicant(s) <b>Wucherpfennig</b>
	Examiner <b>DeCloux, Amy</b>	Group Art Unit <b>1644</b>

Responsive to communication(s) filed on Nov 8, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-20 and 103-113 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-20 and 103-113 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed according to the last section of this office action.
2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-7 and 15-20, drawn to a class II Major Histocompatibility Complex fusion protein comprising the binding domain of an MHC class II  $\alpha$  chain and a dimerization domain, classified in Class 530, subclass 350,
  - II. Claims 8-14, drawn to a class II Major Histocompatibility Complex fusion protein comprising the binding domain of an MHC class II  $\beta$  chain and a dimerization domain, classified in Class 530, subclass 350,
  - III. Claims 103-113, drawn to a class II Major Histocompatibility Complex fusion protein comprising a heterodimer of an MHC class II  $\beta$  chain fusion protein and an MHC class II  $\alpha$  chain fusion protein, classified in Class 530, subclass 350
3. Groups I-III are different products. Group I-III differ with respect to their physicochemical properties because each protein has a distinct amino acid sequence and therefore each has a distinct biochemical properties. Therefore Groups I-III are patentably distinct.
4. Because these inventions I-III are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of the non patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.
5. If Group I or III is elected, the applicant is further required under 35 U.S.C. 121: A) to elect a class II Major Histocompatibility Complex fusion protein comprising

**a specific MHC  $\alpha$  component**, such as one recited in claim 6 or 7.

6. If Group II or III is elected, the applicant is further required:
  - A) to elect a class II Major Histocompatibility Complex fusion protein comprising **a specific MHC  $\beta$  component**, such as one recited in claim 13 or 14.
7. If Group III is elected, the applicant is further required:
  - A) to elect a class II Major Histocompatibility Complex fusion protein comprising **a specific Fc component**, such as IgE, IgM, IgA, IgD, or IgG as recited in claim 107 or 109.
8. Claims 1, 8, 103 and 104 are generic, for example.
9. The species are distinct each from the other for the following reasons:
  - A) The MHC  $\alpha$  components are different products.
  - B) The MHC  $\beta$  components are different products.
  - C) class II Major Histocompatibility Complex fusion proteins comprising different Fc components differ biochemically due to different amino acid sequences, and accordingly have distinct properties and are patentably distinct.
10. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640  
Technology Center 1600  
February 28, 2001

*Mary Tung*  
MARY BETH TUNG, PH.D.  
PATENT EXAMINER